

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION**

STATE OF KANSAS, et al.,

Plaintiffs,

v.

DOROTHY FINK, in her official capacity as
Acting Secretary of the United States
Department of Health and Human Services,
et al.,

Defendants.

Case No. 1:24-cv-00110-LTS-KEM

ANSWER

Defendants Dorothy Fink,¹ in her official capacity as Acting Secretary of the United States Department of Health and Human Services (“HHS”), Stephanie Carlton,² in her official capacity as Acting Administrator of the Centers for Medicare & Medicaid Services (“CMS”), HHS, and CMS, by and through undersigned counsel, hereby answer Plaintiffs’ Amended Complaint (ECF No. 37) as follows, in correspondingly numbered paragraphs:

Plaintiffs’ introductory paragraphs consist of a description of Plaintiffs’ claims in this case, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants admit that Plaintiffs challenge portions of Defendants’ 2024 Final Rule titled *Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, 89 Fed. Reg. 40876 (May 10, 2024) (“Final Rule”). Defendants further admit that the Final Rule was promulgated through a notice and comment rulemaking process, and that, subject to various

¹ Xavier Becerra has been substituted with Dorothy Fink as Acting Secretary of the United States Department of Health and Human Services, pursuant to Federal Rule of Civil Procedure 25(d).

² Chiquita Brooks-Lasure has been substituted with Stephanie Carlton as Acting Administrator of the Centers for Medicare & Medicaid Services, pursuant to Federal Rule of Civil Procedure 25(d).

exemptions and waivers, the Final Rule will require covered facilities to have a registered nurse (“RN”) onsite 24 hours per day, for 7 days a week (the “24/7 RN requirement”), and to maintain at least 0.55 hours per resident per day (“HPRD”) of RN staffing, 2.45 HPRD of nurse aide (“NA”) staffing, and 3.48 HPRD total nurse staffing (the “HPRD requirements”). Defendants admit that the Final Rule also revises Defendants’ previously-existing facility assessment requirement and contains additional institutional payment transparency reporting requirements, neither of which are challenged substantively by Plaintiffs in this case. Defendants deny that any portion of the Final Rule is arbitrary, capricious, contrary to law, violative of the Major Questions Doctrine, or in excess of Defendants’ statutory authority. Defendants further deny that the staffing requirements challenged substantively by Plaintiffs impose any mandatory costs on Plaintiffs prior to the date on which compliance is required under the Final Rule, with the earliest such date being “2 years after the publication date of the final rule,” 89 Fed. Reg. 40910. Defendants deny the remaining allegations in the introductory paragraphs.

1. Defendants admit that Alabama is a State. The remainder of this paragraph consists of Plaintiffs’ characterization of their suit and legal conclusions, not factual allegations to which a response is required.

2. Defendants admit that Alaska is a State. The remainder of this paragraph consists of Plaintiffs’ characterization of their suit and legal conclusions, not factual allegations to which a response is required.

3. Defendants admit that Arkansas is a State. The remainder of this paragraph consists of Plaintiffs’ characterization of their suit and legal conclusions, not factual allegations to which a response is required.

4. Defendants admit that Florida is a State. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required.

5. Defendants admit that Georgia is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

6. Defendants admit that Idaho is a State. The third sentence is denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the sixth sentence. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

7. Defendants admit that Indiana is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

8. Defendants admit that Iowa is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

9. Defendants admit that Kansas is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

10. Defendants admit that Kentucky is a State. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required.

11. Defendants admit that Missouri is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

12. Defendants admit that Montana is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

13. Defendants admit that Nebraska is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

14. Defendants admit that Oklahoma is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

15. Defendants admit that North Dakota is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

16. Defendants admit that South Carolina is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

17. Defendants admit that South Dakota is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

18. Defendants admit that Utah is a State. The remainder of this paragraph consists of Plaintiffs' characterization of their suit and legal conclusions, not factual allegations to which a response is required.

19. Defendants admit that Virginia is a State. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required.

20. Defendants admit that West Virginia is a State. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required.

21. Deny that Medicaid and Medicare reimbursement to nursing homes is underfunded. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

22. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

23. The fourth sentence is denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

24. The third sentence is denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

25. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph, as well as identification of LeadingAge South Carolina members contained in the second sentence. The remainder of the second sentence is denied.

26. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph, as well as the number and identification of LeadingAge Colorado's nursing community members contained in the second sentence. The remainder of the second sentence is denied.

27. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

28. The third sentence is denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

29. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

30. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

31. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

32. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph, as well as the number and identification of LeadingAge Nebraska's nursing home members contained in the second sentence. The remainder of the second sentence is denied.

33. The second sentence is denied. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

34. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

35. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

36. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

37. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first and second sentences of this paragraph. The third sentence is denied.

38. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

39. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

40. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. The second sentence is denied.

41. Deny that Xavier Becerra is the Secretary of Health and Human Services. Defendant Becerra has been substituted with Dorothy Fink as Acting Secretary of the U.S. Department of Health and Human Services, pursuant to Federal Rule of Civil Procedure 25(d). Admit that Defendant Fink oversees the Medicare and Medicaid programs, and is sued in her official capacity.

42. Admit.

43. Admit.

44. Deny that Chiquita Brooks-Lasure is the Administrator of CMS. Defendant Brooks-Lasure has been substituted with Stephanie Carlton as Acting Administrator of CMS, pursuant to Federal Rule of Civil Procedure 25(d). Admit that Defendant Carlton is sued in her official capacity.

45. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, admit that Plaintiffs bring suit under the Administrative Procedure Act (“APA”) and also seek relief under the Declaratory Judgment Act, and deny that Plaintiffs are entitled to any relief.

46. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny that Plaintiffs are entitled to any relief.

47. This paragraph consists of legal conclusions regarding venue, not factual allegations to which a response is required. To the extent a response is deemed required, admit that Plaintiffs State of Iowa and members of LeadingAge Iowa reside in this judicial district and that no real property is involved in this action.

48. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that Plaintiffs purport to challenge the Final Rule under the APA.

49. Admit.

50. Admit.

51. Admit.

52. Admit.

53. Admit.

54. Admit.

55. Admit.

56. Admit that the Medicaid statute includes a provision allowing for the waiver of certain program participation requirements. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of the requirements of the statutory waiver.

57. Admit that the Medicaid statute includes a provision titled “Required nursing care; facility waivers” at 42 U.S.C. § 1396r(b)(4)(C). The remainder of this paragraph consists of legal conclusions and Plaintiffs’ characterizations of the Medicaid and Medicare statutes, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the statutes for a full and accurate statement of their contents.

58. Admit that the Medicare and Medicaid statutes contain the language quoted. Defendants respectfully refer the Court to the text of these statutes for a full and accurate statement of their contents.

59. Admit that the Medicare and Medicaid statutes contain the language quoted. Defendants respectfully refer the Court to the text of these statutes for a full and accurate statement of their contents.

60. This paragraph consists of legal conclusions and Plaintiffs' characterizations of the Medicare statute, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of the requirements of the statutory waiver.

61. Admit that the Medicaid statute contains the language quoted. The remainder of this paragraph consists of legal conclusions and Plaintiffs' characterizations of the Medicaid statute, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of its contents.

62. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

63. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

64. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

65. This paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

66. The first sentence of this paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny. As to the second sentence, Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of its contents.

67. Admit. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of the waiver provisions.

68. Admit that the Department of Health, Education, and Welfare issued proposed rules concerning conditions of participation for nursing homes in the Medicare and Medicaid programs in

1973. The remainder of this paragraph consists of legal conclusions and Plaintiffs' characterization of those proposed rules, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the proposed rule for a full and accurate statement of its contents.

69. Deny except to admit that the agency stated that it received a "suggestion that there be a specific ratio of nursing staff to patients" in the 1974 rule. 39 Fed. Reg. 2238, 2239 (Jan. 17, 1974). Defendants respectfully refer the Court to the text of the rule for a full and accurate statement of its contents.

70. Deny except to admit that the agency did not at the time accept the suggestion that there be a specific ratio of nursing staff to patients. Defendants respectfully refer the Court to the text of the rule for a full and accurate statement of its contents.

71. Admit that the rule contains the language quoted. Defendants respectfully refer the Court to the text of the rule for a full and accurate statement of its contents.

72. Admit that HHS issued a proposed rule concerning conditions of participation in the Medicare and Medicaid programs in 1980. Defendants respectfully refer the Court to the text of the proposed rule for a full and accurate statement of its contents.

73. Deny that HHS made any decision regarding staffing ratios in its 1980 proposed rule. The remainder of this paragraph consists of legal conclusions and Plaintiffs' characterizations of the proposed rule, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the proposed rule for a full and accurate statement of its contents.

74. Admit that the Omnibus Budget Reconciliation Act of 1987 included the requirement that covered facilities must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week. The remainder of this paragraph consists of legal conclusions and Plaintiffs' characterizations of the statute, not factual allegations to which a response is required. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of its contents.

75. Admit that Congress enacted statutory waiver provisions and directed HHS to study the appropriateness of establishing minimum caregiver to resident ratios and minimum supervisor to caregiver ratios for covered nursing homes. Defendants respectfully refer the Court to the text of the statute for a full and accurate statement of its contents.

76. Deny except to admit that CMS did not adopt minimum staffing requirements prior to the Final Rule.

77. Deny except to admit that CMS did not adopt mandatory staffing ratios or a 24/7 RN requirement in 2016. Defendants respectfully refer the Court to the text of the 2016 rule for a full and accurate statement of its contents.

78. Deny except to admit that CMS did not adopt mandatory staffing ratios or a 24/7 RN requirement in 2016. Defendants respectfully refer the Court to the text of the 2016 rule for a full and accurate statement of its contents.

79. Deny except to admit that CMS noted that LTC facilities are varied in their structure and in their resident populations, and that CMS did not adopt mandatory staffing ratios or a 24/7 RN requirement in 2016. Defendants respectfully refer the Court to the text of the 2016 rule for a full and accurate statement of its contents.

80. As to the first sentence, deny except to admit that CMS stated that it “believe[d] that the focus” of its 2016 proposed rule “should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care,” 80 Fed. Reg. 42201. As to the second sentence, deny that CMS made any determination as to the effects or results of establishing a specific number of staff or hours of nursing care in its 2016 proposed rule. Defendants respectfully refer the Court to the text of the 2016 proposed rule for a full and accurate statement of its contents.

81. Deny that CMS made any findings as to the effects of a 24/7 RN requirement in 2016 rule. Defendants respectfully refer the Court to the text of the 2016 rule for a full and accurate statement of its contents.

82. As to the first sentence, admit. As to the second sentence, admit that the 2016 rule contains the language quoted, and deny that CMS's 2016 rule amounted to a rejection of minimum staffing requirements. Defendants respectfully refer the Court to the text of the 2016 rule for a full and accurate statement of its contents.

83. Admit that many States have independently set minimum staffing requirements for nursing homes. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

84. Admit that the White House Fact Sheet cited contains the language quoted. Defendants respectfully refer the Court to the text of the White House Fact Sheet for a full and accurate statement of its contents.

85. Admit. Defendants respectfully refer the Court to the text of the White House Fact Sheet for a full and accurate statement of its contents.

86. Admit that CMS commissioned Abt Associates to perform a research study ("2022 Abt Study") to determine the level and type of staffing needed to ensure safe and quality care for nursing home residents with the goal of developing proposed rules in 2023.

87. Admit that the 2022 Abt Study contains the language quoted. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

88. As to the first sentence, admit. As to the second sentence, deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

89. Admit that the 2022 Abt Study stated that “[n]ursing homes face many barriers to hiring, primarily workforce shortages and competition from staffing agencies.” 2022 Abt Study at xiv, 115. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

90. As to the first sentence, admit that “[q]uantitative analyses found that between 42 and 90 percent of nursing homes would need to increase staffing under a federal minimum staffing requirement, depending on the requirement level and design.” *Id.* at 113. As to the second sentence, admit that the 2022 Abt Study estimated total costs between \$2.2 and \$6.8 billion annually. *Id.* As to the third sentence, deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

91. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

92. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

93. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

94. Deny that the prior rules cited amounted to a rejection of the minimum staffing requirements at issue in this case. Defendants respectfully refer the Court to the rules cited for a full and accurate statement of their contents.

95. Deny that the 2022 Abt Study does not support the minimum staffing requirements at issue in this case. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

96. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

97. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

98. Admit that CMS issued the proposed rule in September 2023.

99. Admit that CMS received over 46,000 public comments expressing a range of views in response to its proposed rule. Defendants further admit that the Final Rule was published in May 2024. Defendants respectfully refer the Court to the text of the Final Rule and the comments for a full and accurate statement of their contents.

100. Admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

101. Defendants deny that the 2022 Abt Study was inconclusive or truncated, and further deny that the minimum staffing requirements are overly-broad or onerous. Admit that Defendants determined that the minimum staffing requirements are necessary to protect resident health, safety, and well-being. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

102. Admit that the Final Rule describes one takeaway of the 2022 Abt Study using the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

103. Deny that the 2022 Abt Study was inconclusive, and deny that CMS has consistently rejected a minimum staffing requirement for over fifty years. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents. Admit that CMS published the Final Rule.

104. Admit that the Defendants' authority to promulgate the Final Rule is supported by multiple statutory provisions. Defendants respectfully refer the Court to the text of the statutes and the Final Rule for a full and accurate statement of their contents.

105. Admit that the Final Rule imposes two minimum-staffing requirements on covered LTC facilities, subject to exemptions and waivers. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of these requirements.

106. Admit that the statutes and Final Rule contain the language quoted. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

107. Admit that the statutes and Final Rule contain the language quoted. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

108. Admit that prior to publication of the Final Rule, Defendants' regulations did not include 24/7 RN or HPRD requirements for minimum nurse staffing, and deny that all of Defendants' regulations mirrored the statutory requirements related to staffing prior to publication of the Final Rule. Defendants respectfully refer the Court to the text of the statutes and preexisting regulations for a full and accurate statement of their contents.

109. As to the first sentence, deny. As to the second sentence, admit that the HPRD requirements apply regardless of the individual facility's resident case-mix as they are the minimum standard of staffing, and deny that the minimum staffing requirements were formulated without regard to case-mix adjusted data. The remainder of this paragraph consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

110. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the waivers.

111. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the waivers.

112. As to the first sentence, admit that the Final Rule contains a regulatory hardship exemption. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the exemption. As to the second sentence, deny.

113. Defendants admit that the Final Rule contains a regulatory hardship exemption, and respectfully refer the Court to the text of the Final Rule for a full and accurate description of the exemption requirements.

114. As to the first sentence, deny. As to the second sentence, admit that the regulatory hardship exemption allows for exemption from 8 hours per day of the 24/7 RN requirement, with facilities remaining free to seek an additional waiver as to the remaining hours pursuant to the requirements of the existing statutory waiver. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the exemption.

115. As to the first sentence, admit that a facility will not be eligible for a regulatory hardship exemption if it is a Special Focus Facility, has been cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm, or has been cited at the “immediate jeopardy” level of severity with respect to insufficient staffing within the 12 months preceding the survey during which non-compliance is identified. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the exemption. As to the second sentence, deny.

116. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

117. Deny. Defendants respectfully refer the Court to the text of the 2022 Abt Study for a full and accurate statement of its contents.

118. As to the first sentence, deny. As to the second sentence, admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

119. Deny. Defendants respectfully refer the Court to the text of the proposed rule for a full and accurate statement of its contents.

120. Admit. Defendants respectfully refer the Court to the text of the proposed rule for a full and accurate statement of its contents.

121. Deny. Defendants respectfully refer the Court to the text of the proposed rule and the 2022 Abt Study for a full and accurate statement of their contents.

122. Deny. Defendants respectfully refer the Court to the text of the proposed rule and Final Rule for a full and accurate statement of their contents.

123. Deny. Defendants respectfully refer the Court to the text of the proposed and Final Rule for a full and accurate statement of their contents.

124. Admit that some facilities with higher acuity residents may need to staff at levels above the minimum-staffing requirements imposed by the Final Rule, but otherwise deny the allegations in this paragraph. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

125. As to the first sentence, deny. As to the second sentence, admit that the Final Rule requires the use of Payroll Based Journaling (“PBJ”) data, *inter alia*, to monitor and enforce the HPRD and 24/7 requirements. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

126. As to the first, second, and third sentences, deny except to admit that PBJ data does not describe staffing on a shift-by-shift basis. The fourth sentence consists of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

127. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

128. As to the first sentence, deny that Defendants failed to address the workforce shortage, and admit that CMS announced a \$75 million campaign to expand the nursing workforce by providing financial incentives to work in nursing homes. As to the second and third sentences, deny that the campaign will be ineffective or fail to address any workforce shortage. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

129. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

130. As to the first sentence, admit that CMS estimated the total cost for the Final Rule to exceed \$5 billion per year in years five through ten, not including adjustments for any exemptions that CMS may provide. As to the second sentence, admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its cost estimates.

131. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

132. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

133. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of the cost estimates.

134. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first and fourth sentences of this paragraph. As to the second, third, and fifth sentences, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of the cost estimates.

135. Deny that the costs of compliance with the Final Rule will be prohibitive. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its

estimated costs. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

136. Deny that Medicaid and Medicare reimbursement to nursing homes is underfunded. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

137. Admit that the Final Rule will have costs for facilities that do not already meet the minimum staffing requirements and do not qualify for an exemption or waiver. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its estimated costs.

138. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

139. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

140. Deny that the Final Rule requires facilities to incur any cost for increased staffing prior to two years from the date of the rule's publication at the earliest. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

141. Deny that the Final Rule requires facilities to incur any cost for increased staffing prior to two years from the date of the rule's publication at the earliest. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

142. Deny that the Final Rule requires facilities to incur any cost for increased staffing prior to two years from the date of the rule's publication at the earliest. Defendants lack knowledge or

information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

143. Deny.

144. Deny that the Final Rule requires facilities to incur any cost for increased staffing prior to two years from the date of the rule's publication at the earliest. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

145. Deny that the Final Rule requires facilities to incur any cost for increased staffing prior to two years from the date of the rule's publication at the earliest. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

146. Deny.

147. Deny.

148. As to the first sentence, admit that CMS has announced a \$75 million campaign to expand the nursing workforce. As to the second sentence, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its estimated costs.

149. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first and second sentences of this paragraph. As to the third sentence, deny.

150. As to the first sentence, admit that the requirements of the Final Rule will impact a majority of LTC facilities across the country. As to the second and third sentences, admit that the Final Rule's requirements are estimated to increase staffing in more than 79 percent of nursing facilities nationwide, and that the specific RN and NA HPRD requirements exceed the existing minimum

staffing requirements in nearly all States. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement its contents.

151. Admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding RN hiring.

152. As to the first sentence, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding NA hiring. As to the second sentence, deny.

153. As to the first sentence, deny that the Final Rule causes imminent irreparable harm to Plaintiffs. As to the second sentence, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding RN hiring.

154. Deny that the Final Rule requires facilities to come into compliance with the 24/7 RN requirement prior to two years from the date of the rule's publication at the earliest. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding the number of facilities needing RNs, and the number of NAs needed.

155. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

156. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

157. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding RN hiring.

158. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding NA hiring.

159. Deny that the Final Rule requires facilities to come into compliance with the staffing requirements prior to two years from the date of the rule's publication at the earliest. Defendants

respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding the number of facilities needing RNs and NAs.

160. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

161. As to the first sentence, admit that more than half of the counties in Montana are designated as HPSAs. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in this paragraph.

162. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding RN hiring.

163. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates regarding NA hiring. As to the second sentence, deny that CMS's estimates are incorrect.

164. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

165. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. As to the second sentence, deny.

166. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

167. Defendants respectfully refer the Court to the text of the cited statute for a full and accurate statement of Virginia's impending state law HPRD requirement.

168. The first sentence of this paragraph consists of legal conclusions, not a factual allegation to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of Defendants' consideration of these issues. As to the second sentence, deny.

169. Admit that the Final Rule contains an Enhanced Facility Assessment (“EFA”) provision, which builds on the existing facility assessment requirement. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

170. As to the first sentence, admit that the Final Rule contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the second sentence of this paragraph.

171. Admit that the Final Rule requires facilities to review and update the facility assessment at least annually, and deny that insufficient guidance is provided as to when such updates are necessary. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

172. Admit that the Final Rule requires facilities to use the facility assessment to inform contingency planning for events that do not necessarily require the activation of the facility’s emergency plan but do have the potential to impact resident care. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents. The second sentence is denied.

173. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

174. As to the first sentence, Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS’s estimates for the cost of the EFA provisions. As to the second sentence, deny.

175. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

176. Deny that CMS's cost estimates are inaccurate. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's estimates for the cost of the EFA provisions.

177. Admit.

178. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

179. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

180. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph

181. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

182. Deny.

183. Deny.

184. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in this paragraph.

185. Deny.

186. Deny.

187. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations contained in the first sentence of this paragraph. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of the estimated costs for implementation of the requirements.

188. Admit. Defendants respectfully refer the court to the text of the Final Rule for a full and accurate statement of the institutional payment transparency reporting requirements.

189. Admit that States are not required to comply with the institutional payment transparency reporting requirements until 4 years from the effective date of the Final Rule. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of estimated costs associated with the institutional payment transparency reporting requirements.

190. Defendants repeat their answers to the foregoing paragraphs.

191. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the APA contains the language quoted.

192. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

193. Deny.

194. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the Final Rule conflicts with the statute. To the extent this paragraph relies upon citations to statute, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

195. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the Final Rule conflicts with the statute. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its contents.

196. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its contents.

197. Admit that CMS cited multiple sources of statutory authority for the Final Rule. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its authorities.

198. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the Final Rule lacks statutory authority.

199. Admit that the statutes contain the language quoted. Defendants respectfully refer the Court to the text of the statutes for a full and accurate description of their contents.

200. Admit that the statutes contain the language quoted. Defendants respectfully refer the Court to the text of the statutes for a full and accurate description of their contents.

201. Admit that the statutes contain the language quoted. Defendants respectfully refer the Court to the text of the statutes for a full and accurate description of their contents.

202. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

203. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

204. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

205. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its contents.

206. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

207. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

208. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the statutes preclude Defendants from adopting the HPRD requirements.

209. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny except to admit that the Final Rule requires covered facilities to provide a minimum of 3.48 HPRD for total nurse staffing, including but not limited to a minimum of 0.55 HPRD for RNs; and a minimum of 2.45 HPRD for NAs, absent an exemption or waiver. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its contents.

210. Admit.

211. Deny except to admit that CMS relied on multiple sources of statutory authority for the Final Rule. Defendants respectfully refer the Court to the text of the statutes and Final Rule for a full and accurate description of their contents.

212. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

213. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the HPRD requirements conflict with the statutes.

214. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

215. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

216. As to the first sentence, admit that CMS estimated the total cost of the Final Rule, not including any waivers which may lower the final cost, to be \$4.3 billion on average per year over ten years. As to the second sentence, deny that CMS's cost estimates are inaccurate. The third sentence consists of a legal conclusion, not factual allegations to which a response is required. To the extent this paragraph relies on case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

217. As to the first two sentences, deny. As to the third sentence, admit that the Final Rule contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

218. Admit that 38 States and the District of Columbia have state level minimum nursing staffing standards. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents. The remaining allegations in this paragraph consist of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

219. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

220. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

221. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

222. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

223. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

224. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. To the extent this paragraph relies upon case citations, Defendants respectfully refer the Court to those sources for a full and accurate statement of their contents.

225. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

226. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the case cited contains the language quoted. Defendants respectfully refer the Court to the case cited for a full and accurate statement of its contents.

227. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the Court should adopt a narrowing construction here. Defendants respectfully refer the Court to the case cited for a full and accurate statement of its contents.

228. Defendants repeat their answers to the foregoing paragraphs.

229. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

230. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. Defendants respectfully refer the Court to the case cited for a full and accurate statement of its contents.

231. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the statutes cited contain the language quoted, and deny that the Final Rule rewrites the statutory requirement. Defendants respectfully refer the Court to the statutes cited for a full and accurate statement of their contents.

232. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the Final Rule contains the language quoted, and deny that the Final Rule conflicts with the statute. Defendants respectfully refer the Court to the Final Rule for a full and accurate statement of its contents.

233. Deny. Defendants respectfully refer the Court to the statutes cited for a full and accurate statement of their contents.

234. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

235. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

236. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the Final Rule and statutes contain the language quoted, and deny that the Final Rule conflicts with the statutes.

Defendants respectfully refer the Court to the statutes and Final Rule for a full and accurate statement of their contents.

237. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

238. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the Final Rule and statutes contain the language quoted. Defendants respectfully refer the Court to the statutes and Final Rule for a full and accurate statement of their contents.

239. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny except to admit that the Final Rule requires covered facilities to provide a minimum of 3.48 HPRD for total nurse staffing, including but not limited to a minimum of 0.55 HPRD for RNs; and a minimum of 2.45 HPRD for NAs, absent an exemption or waiver. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of its contents.

240. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

241. Defendants repeat their answers to the foregoing paragraphs.

242. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, admit that the APA contains the language quoted.

243. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

244. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the cases cited for a full and accurate statement of their contents.

245. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the case cited for a full and accurate statement of its contents.

246. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the cases cited for a full and accurate statement of their contents.

247. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

248. Admit that CMS has not required nursing homes to provide a specific ratio of nursing staff to patients. Defendants respectfully refer the Court to the rules cited for a full and accurate statement of their contents. The remaining allegations in this paragraph consist of legal conclusions, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

249. Admit that the Institute of Medicine study cited contains the language quoted. Defendants respectfully refer the Court to the study for a full and accurate statement of its contents.

250. Admit that Secretary of HHS did not recommend requiring minimum staffing ratios in 2002, due to reservations about the reliability of staffing data at the nursing home level. Defendants respectfully refer the Court to the Thompson Letter for a full and accurate statement of its contents.

251. Admit that CMS did not adopt minimum staffing requirements in 2016, and deny that CMS made any determination as to the reasonableness of minimum staffing requirements in its 2016

rule. Defendants respectfully refer the Court to the 2016 rule for a full and accurate statement of its contents.

252. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

253. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

254. Deny except to admit that some states have enacted state level minimum staffing requirements in addition to the longstanding requirements promulgated by Defendants.

255. Admit that State Medicaid rates for nursing home services vary, and that the rule cited contains the language quoted. Defendants respectfully refer the Court to the text of the cited rules for a full and accurate statement of their contents.

256. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

257. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny except to admit that the Final Rule contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

258. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the statute cited for a full and accurate description of its contents.

259. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the regulation cited for a full and accurate description of its contents.

260. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the regulation cited for a full and accurate description of its contents.

261. The first sentence of this paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the regulation cited for a full and accurate description of its contents. As to the second sentence, deny.

262. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the regulation cited for a full and accurate description of its contents.

263. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the legislation cited for a full and accurate description of its contents.

264. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants respectfully refer the Court to the regulation cited for a full and accurate description of its contents.

265. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, Defendants admit that the Final Rule contains the language quoted, and deny that the minimum staffing requirements are not necessary for resident health, safety, and well-being. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

266. Admit that the comment cited contains the language quoted. Defendants respectfully refer the Court to the text of the comment for a full and accurate statement of its contents.

267. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

268. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

269. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

270. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

271. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

272. Admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

273. Admit that CMS provided estimates of the number of additional nursing staff needed in the Final Rule and considered such data when promulgating the minimum staffing requirements. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of CMS's RN and NA hiring estimates.

274. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

275. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

276. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the Final Rule failed to

account for any incentive to terminate LPN/LVNs. Defendants respectfully refer the Court to the text of the proposed and Final Rule for a full and accurate statement of Defendants' consideration of LPNs and LVNs.

277. Admit that Defendants considered that facilities may be incentivized to terminate LPN/LVNs and replace them with either nurse aides, RNs or a lower paid unlicensed staff, and reasonably concluded that a total nurse staffing standard guards against these unintended consequences. Defendants respectfully refer the Court to the text of the proposed and Final Rule for a full and accurate statement of Defendants' consideration of LPNs and LVNs.

278. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that Defendants' consideration of LPNs and LVNs was inadequate or unreasonable. Defendants respectfully refer the Court to the text of the proposed and Final Rule for a full and accurate statement of Defendants' consideration of LPNs and LVNs.

279. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

280. Deny that facilities will be unable to meet the minimum staffing requirements.

281. Admit that the Final Rule contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

282. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

283. Admit that the comments cited contain the language quoted and deny that the Final Rule's phase-in period is insufficient to address any staffing shortage for purposes of compliance with the minimum staffing requirements. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its consideration of workforce shortage issues.

284. Deny except to admit that the Final Rule contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

285. Deny except to admit that the comment cited contains the language quoted. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of Defendants' consideration of the phase-in period.

286. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

287. Admit that facilities cannot request a survey specifically for the purpose of granting a hardship exemption. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

288. Deny. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

289. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny that the hardship exemption is insufficient.

290. Admit that the Final Rule contains the language quoted, and deny that many facilities in areas of the country with severe shortages of available RNs and NAs would not qualify for an exemption. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

291. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

292. As to the first sentence, admit that CMS estimated the total cost for the Final Rule to exceed \$5 billion per year in years five through ten, not including adjustments for any exemptions that

CMS may provide. As to the second sentence, admit. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its cost estimates.

293. Admit that the Final Rule itself does not provide a new source of funding for Medicare or Medicaid, though additional staffing costs ultimately will be factored into Medicare reimbursement through preexisting processes. Defendants further admit that CMS acknowledged there is uncertainty about the degree to which LTC facilities would bear the cost of meeting the minimum staffing requirements, but assumed for purposes of its cost estimates that LTC facilities will bear the rule's cost. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its cost estimates.

294. Deny that covered facilities will be unable to implement the requirements of the Final Rule. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its estimated costs.

295. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

296. Admit that CMS announced a \$75 million campaign to expand the nursing workforce by providing financial incentives to work in nursing homes. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

297. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

298. Admit that the EFA requirement took effect on August 8, 2024. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the EFA requirement.

299. Admit that facilities are required to comply with the EFA requirement, and deny that the EFA requirement imposes a significant burden on LTC facilities as compared to the preexisting

facility assessment requirement which the EFA requirement supplements. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate description of the estimated costs of the EFA requirement.

300. Admit that the Final Rule requires facilities to review and update the facility assessment at least annually, and deny that insufficient guidance is provided as to when such updates are necessary. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

301. Admit that the Final Rule requires facilities to use the facility assessment to inform contingency planning for events that do not necessarily require the activation of the facility's emergency plan but do have the potential to impact resident care. Defendants respectfully refer the Court to the text of the Final Rule for a full and accurate statement of its contents.

302. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

303. This paragraph consists of a legal conclusion, not factual allegations to which a response is required. To the extent a response is deemed required, deny.

The remainder of the Amended Complaint contains Plaintiffs' requested relief, not factual allegations to which a response is required. To the extent that a response is deemed required, Defendants deny that Plaintiffs are entitled to any relief.

Defendants deny all allegations in Plaintiffs' Amended Complaint not expressly admitted or denied herein to which a response is deemed required.

DEFENSES

1. Plaintiffs' Amended Complaint fails to allege facts sufficient to state a plausible claim for relief as to the Enhanced Facility Assessment or institutional payment transparency reporting requirements of the Final Rule.

2. Defendants at all relevant times acted in accordance with applicable legal authority, and did not violate the APA, or any other applicable statute, regulation, or legal authority, and Plaintiffs are not entitled to any relief.

Dated: February 6, 2025

Respectfully submitted,

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